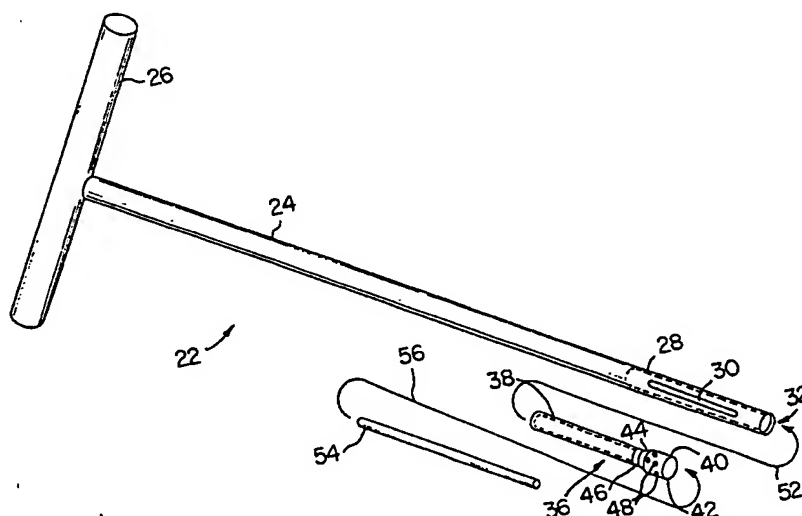


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(54) Title: BIOPSY DEVICE**(57) Abstract**

A biopsy device (22) for obtaining biopsy specimens from hard or soft tissue includes a biopsy trocar (22) which may be inserted into a cannula and a removable biopsy specimen holder (36) which is preferably threaded into the biopsy trocar. The specimen holder preferably includes a cutting edge (42) (e.g., serrated for hard tissue, slicing for soft tissue), and retaining fish-scales or scallop members (48) securely holding the biopsy specimen. Once the biopsied specimen is cut from the tissue, it may be sent, within the removable specimen holder, to the pathologist for analysis.

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WO 91/06246

PCT/US90/06268

- 1 -

BIOPSY DEVICEBackground of the Invention

The present invention relates to devices for taking hard tissue or soft tissue biopsy specimens.

Biopsies are taken when a small tissue specimen is required for examination, e.g., by a pathologist, particularly in cases where cancer is suspected.

More than one million tissue (hard and soft) biopsies are presently performed each year in the United States. Soft tissue biopsies are performed by surgeons of all specialties as well as by some oncologists. Hard tissue (bone) biopsies are performed primarily by three types of physicians: orthopaedic surgeons, oncologists (usually orthopaedic), and radiologists. Although the vast majority of all biopsies performed are of soft tissue biopsies, the number of bone biopsies has been growing rapidly over the past few years. Biopsies are used in both human and veterinary medicine.

Summary of the Invention

A general feature of the invention is a biopsy device for obtaining either hard (bone) or soft tissue biopsy specimens including a biopsy trocar adapted for insertion into a cannula, and a biopsy specimen holder removably attached, preferably by threaded engagement, to one end of the biopsy

WO 91/06246

PCT/US90/06268

- 2 -

trocar. In a preferred embodiment, the specimen holder has an inside diameter on the order of 2.4 mm. (1.2 mm. in a sternal version), and includes an elongated, substantially transparent, plastic tubular portion which fits within the biopsy trocar, and a cutting portion, having either a serrated or slicing edge, which extends from one end of the biopsy trocar. In another preferred embodiment, the biopsy trocar includes a handle and at least one viewing portal for viewing a biopsy specimen held within the tubular portion of the specimen holder. Preferably also, the specimen holder includes a plurality of inwardly extending scallop-like retaining members formed by perforations in the cutting portion, or fishscale-like retaining members formed by machining material from the interior of the cutting portion, either of which is adapted to inhibit movement of the biopsy specimen in at least one longitudinal direction. The biopsy device also preferably includes a sharply pointed starter trocar (obturator) which may be inserted into the cannula in place of the biopsy trocar.

Another general feature of the invention is a method for obtaining either a soft or hard tissue biopsy specimen from a surgical site, which includes the steps of inserting a sharply-pointed starter trocar into a cannula, whereby the sharply pointed end of the trocar extends from the cannula; pushing the cannula-enclosed starter trocar into the surgical site; removing the starter trocar from the cannula; inserting a

WO 91/06246

PCT/US90/06268

- 3 -

biopsy trocar having a removable specimen holder into the cannula, the specimen holder having a cutting portion which extends from the biopsy trocar; twisting the biopsy trocar within the cannula against tissue, whereby the tissue is cut by the cutting portion and the cut tissue is held within the specimen holder; removing the biopsy trocar from the surgical site; removing the specimen holder from the biopsy trocar; and pushing the tissue out of the specimen holder, whereby the tissue may be examined by a pathologist. Preferred methods of performing the invention include pushing the cannula-enclosed starter trocar against a bone, sawing the bone with the cutting portion, and unscrewing the specimen holder from said biopsy trocar in advance of pathological examination.

Description of the Preferred Embodiments

The drawings are first briefly described:

Figs. 1A-1C are perspective views showing the interrelationship among two components of a biopsy device in accordance with a preferred embodiment of the present invention;

Figs. 2A-2C are perspective views showing the interrelationship among three further components of a biopsy device in accordance with a preferred embodiment of the present invention;

Figs. 3A-3B are side elevation and end views, respectively, of a portion of a biopsy device in accordance with a preferred embodiment of the present invention;

WO 91/06246

PCT/US90/06268

- 4 -

Fig. 4 is a cross-sectional view of a portion of a biopsy device taken along the line 4-4 of Fig. 3B;

Fig. 5 is a cross-sectional view of a portion of a biopsy device in accordance with an alternate preferred embodiment of the present invention;

Fig. 6 is a schematic view, with internal structure in phantom, of a portion of a biopsy device in accordance with another preferred embodiment of the present invention.

Structure

Figs. 1A-4 depict one embodiment of a biopsy device in accordance with the present invention. Referring to Figs. 1A-1C, there is a hollow, cylindrical cannula 10 having a tapered end 12. A solid cylindrical starter trocar 14, having a sharply pointed end 16 and a stop member 18, is insertable into the cannula 10 as indicated by assembly arrow 20. The stop member 18 serves to limit the extent to which the sharply pointed end 16 of the starter trocar 14 extends from the cannula 10, as can be most clearly seen from Fig. 1C.

Referring to Fig. 2A, there is a biopsy trocar 22 having cylindrical body portion 24 and a T-handle end 26. The biopsy trocar 24 is insertable into the cannula 10. The end of the body portion 24 opposite the T-handle end 26 is hollow, as shown by the dashed line 28 in Fig. 2A. There are a pair of longitudinal slots 30 or viewing portals in the sidewall of the biopsy trocar 22 in the vicinity of the hollow area 28, and

WO 91/06246

PCT/US90/06268

- 5 -

there is an internal thread 32 at the end of the biopsy trocar.

The cannula 10, starter trocar 14, and biopsy trocar 22 are all fabricated from surgical-grade stainless steel, and can all be used to obtain either hard tissue or soft tissue biopsy specimens.

Referring to Figs. 2B, 3A, 3B, and 4, there is a disposable bone blade/cartridge assembly 36. The cartridge assembly 36 includes an elongated clear plastic tubular portion 38 and a stainless steel cutting portion 40. The cutting portion 40 has a serrated cutting edge 42, an external thread 44, a pair of holes 46, and a plurality of scallop retaining members 48.

As can be most clearly seen from Figs. 3A, 3B and 4, the scallop retaining members 48 which are formed by perforations in the wall of the cutting portion 40, extend inwardly and away from the serrated cutting edge 42. Thus, they permit a biopsy specimen to easily slide into the cartridge assembly 36, but act to prevent the specimen from sliding out of the cartridge, e.g., when the biopsy trocar is removed from the bone.

As indicated by assembly arrow 52, the blade/cartridge assembly 36 may be removably attached to the biopsy trocar 24 by inserting the tubular portion 38 into the hollow area 28 and engaging external thread 44 with internal thread 32. The holes

WO 91/06246

PCT/US90/06268

- 6 -

46 facilitate disassembly of the blade/cartridge assembly 36 from the biopsy trocar 24, by permitting a pin (not shown) to be inserted therein to serve as a lever to aid in unscrewing the cartridge assembly from the trocar.

Referring to Fig. 2C, a plastic pusher 54 is shown which, in accordance with assembly arrow 56, may be inserted into the cartridge assembly 36 to push out the biopsy specimen.

As an alternative to the scallop retaining members 48, fishscale retaining members 60 may be used as shown in the alternate embodiment of a bone blade/cartridge assembly 62 of in Fig. 5. Except for the use of fishscale retaining members 60 in place of scallop retaining members 48, the bone blade/cartridge assembly 62 corresponds generally to the bone blade cartridge assembly 36, and includes a cutting portion 40', a serrated cutting edge 42', an external thread 44', and a pair of holes 46', all of which correspond respectfully to the elements 40, 42, 44 and 46 of the bone blade/cartridge assembly 36. The fishscale retaining members 60 are formed by machining annular grooves into the interior surface of the cutting portion 40' of the bone blade/cartridge assembly 62. As shown, the fishscale retaining members 60 extend inwardly and away from the serrated cutting edge 42'.

Referring now to Fig. 6, there is a soft-tissue blade/cartridge assembly 66 in accordance with an alternate

WO 91/06246

PCT/US90/06268

- 7 -

embodiment of the present invention. The soft-tissue blade/cartridge assembly 66 is generally similar to the bone blade/cartridge assembly 36, and may be threaded into the biopsy trocar 22. The major difference between the bone blade/cartridge assembly 36 and the soft-tissue blade/cartridge assembly 66 is that the former has a serrated cutting edge 42 for sawing through bone, whereas the latter has a sharp knife-like slicing edge 68 for cutting soft tissue. Otherwise, the soft-tissue blade/cartridge assembly 66 includes a clear plastic tubular portion 38'', an external thread 44'', a pair of holes 46'' to assist in unscrewing, and a plurality of scallop retaining members 48'', all of which correspond generally to the elements 38, 44, 46 and 48 of the bone blade/cartridge assembly 36.

Procedure

For either bone or hard tissue, the patient is first properly positioned, a surgical scrub done and, using the proper anesthetic in the proper setting (such as the operating room or clinic), a small incision is made in the skin. Aseptic technique is used throughout the procedures.

Use of the biopsy device of the present invention to obtain a bone biopsy specimen is first described.

The starter trocar 14 is first inserted into the cannula 10 with the sharp end 16 of the starter trocar extending from the cannula. The sharp end 16 is then inserted

WO 91/06246

PCT/US90/06268

- 8 -

into the incision at the surgical site and gently pushed through the soft tissues until it abuts bone. The cannula 10 is then slipped down over the starter trocar 14 the last few millimeters until it is also abutting bone. A bone blade/cartridge assembly 36 has previously been screwed onto the end of the biopsy trocar 22 opposite the T-handle end 26. The starter trocar 14 is then removed from the cannula 10, and the biopsy trocar 22 inserted down to the bone.

The operator then holds the cannula 10 snugly against the bone and begins twisting the biopsy trocar 22 in a clockwise motion, holding onto the T-handle end 26. Gentle pressure is applied so that the serrated cutting edge 42 cuts through the cortical aspect of the bone, pushing a core biopsy of bone and underlying cancellous bone into the bone blade/cartridge assembly 36 as the biopsy trocar 22 advances into the bone.

When the proper depth has been reached, the operator continues to hold the cannula 10 snugly against the bone and removes the biopsy trocar 22 by pulling on the T-handle end 26 and removing it from the bone. Gentle clockwise motion may facilitate removal of the biopsy trocar. Counterclockwise motion should be avoided as it potentially could cause the blade/cartridge assembly 36 to unscrew from the biopsy trocar 22.

WO 91/06246

PCT/US90/06268

- 9 -

The longitudinal slots 30 in the end of the biopsy trocar 22 permit viewing of the clear plastic tubular portion 38 of the bone blade/cartridge assembly 36 allowing the operator to observe that a tissue specimen has been obtained. The scallop retaining members 48 along the inner surface of the bone blade/cartridge assembly 36 (or alternatively, the fishscale retaining members 60 in the event the alternate bone blade/cartridge assembly 62 is used) allows the biopsied bone specimen to slide into the cartridge easily; but, because of the shape of the scallop (or fishscale) retaining members, the bone is securely held in the cartridge when the biopsy trocar 22 is pulled out of the bone. The bone blade/cartridge assembly 36, containing the biopsied bone specimen, is then unscrewed from the biopsy trocar 22 and sent to the pathologist with the biopsy tissue intact within the cartridge.

The pathologist then inserts the plastic pusher 54 into the serrated cutting edge end (42) of the bone blade/cartridge assembly 36 to remove the biopsy specimen. By obtaining the bone biopsy in this method, the pathologist can better understand the normal alignment of the bony tissue which is biopsied. The bone blade/cartridge assembly 36 may then be discarded. By so doing, a new sharp blade is available for use for each biopsy.

Essentially, the same procedure is used for obtaining soft tissue biopsy specimens. The only difference being that

WO 91/06246

PCT/US90/06268

- 10 -

the soft-tissue blade/cartridge assembly 66 is used in place of the bone blade/cartridge assembly 36. The soft-tissue blade/cartridge assembly 66 has a sharp cutting or slicing edge 68 instead of a serrated cutting edge 42, making the biopsy of soft tissue easier.

WO 91/06246

PCT/US90/06268

- 11 -

What is claimed is:

1. A biopsy device comprising:
a biopsy trocar adapted for insertion into a cannula;
and
a biopsy specimen holder removably attached to one end
of said biopsy trocar.
2. The biopsy device of claim 1 wherein both said
biopsy trocar and said specimen holder are threaded, whereby
said removable attachment may be achieved by engagement of the
threads on said biopsy trocar with the threads on said specimen
holder.
3. The biopsy device of claim 1 wherein said specimen
holder includes an elongated tubular portion, and a cutting
portion which extends from said one end of said biopsy trocar.
4. The biopsy device of claim 3 wherein said cutting
portion includes a serrated cutting edge.
5. The biopsy device of claim 3 wherein said cutting
portion includes a slicing edge.
6. The biopsy device of claim 3 wherein said
elongated tubular portion is substantially transparent.

WO 91/06246

PCT/US90/06268

- 12 -

7. The biopsy device of claim 6 wherein said biopsy trocar includes at least one viewing portal adjacent said tubular portion when said specimen holder is attached to said biopsy trocar, whereby a specimen held within said specimen holder may be viewed.

8. The biopsy device of claim 6 wherein said elongated tubular portion is plastic.

9. The biopsy device of claim 1 wherein said biopsy trocar further includes a handle at the end opposite said one end.

10. The biopsy device of claim 3 wherein said specimen holder includes at least one inwardly extending retaining member adapted to inhibit movement of any specimen contained within said specimen holder in at least one longitudinal direction.

11. The biopsy device of claim 10 wherein said specimen holder includes a plurality of inwardly extending scallop retaining members formed by perforations in said cutting portion.

WO 91/06246

PCT/US90/06268

- 13 -

12. The biopsy device of claim 10 wherein said specimen holder includes a plurality of inwardly extending fishscale retaining members formed by machining the interior surface of said cutting portion.

13. The biopsy device of claim 1 further comprising a sharply pointed starter trocar adapted for insertion into said cannula.

14. The biopsy device of claim 1 wherein said specimen holder has an inner diameter of approximately 2.4 mm.

15. The biopsy device of claim 1 wherein said specimen holder has an inner diameter of approximately 1.2 mm.

16. In a device for obtaining biopsy specimens of the type including a cannula, and a sharply pointed started trocar adapted for insertion into the cannula, the improvement comprising:

a biopsy trocar adapted for insertion into the cannula; and

a cylindrically-shaped biopsy specimen holder threadably attached to one end of said biopsy trocar.

WO 91/06246

PCT/US90/06268

- 14 -

17. The biopsy device of claim 16 wherein said specimen holder includes an elongated tubular portion, and a cutting portion having a serrated cutting edge which extends from said one end of said biopsy trocar.

18. The biopsy device of claim 16 wherein said specimen holder includes an elongated tubular portion adapted to fit within said biopsy trocar, and a cutting portion having a slicing edge which extends from one end of said biopsy trocar.

19. The biopsy device of claim 16 wherein said specimen holder includes a plurality of perforations forming inwardly extending retaining members.

20. A method for obtaining a tissue biopsy specimen from a surgical site, comprising:

inserting a sharply-pointed starter trocar into a cannula, whereby the sharply pointed end of said trocar extends from said cannula;

pushing said cannula-enclosed starter trocar into said surgical site;

removing said starter trocar from said cannula;

inserting a biopsy trocar having a removable specimen holder into said cannula, said specimen holder having a cutting portion which extends from said biopsy trocar;

WO 91/06246

PCT/US90/06268

- 15 -

twisting said biopsy trocar within said cannula
against tissue, whereby the tissue is cut by said cutting
portion and the cut tissue is held within said specimen holder;
removing said biopsy trocar from said surgical site;
removing said specimen holder from said biopsy trocar;
and
pushing the tissue out of said specimen holder,
whereby the tissue may be examined.

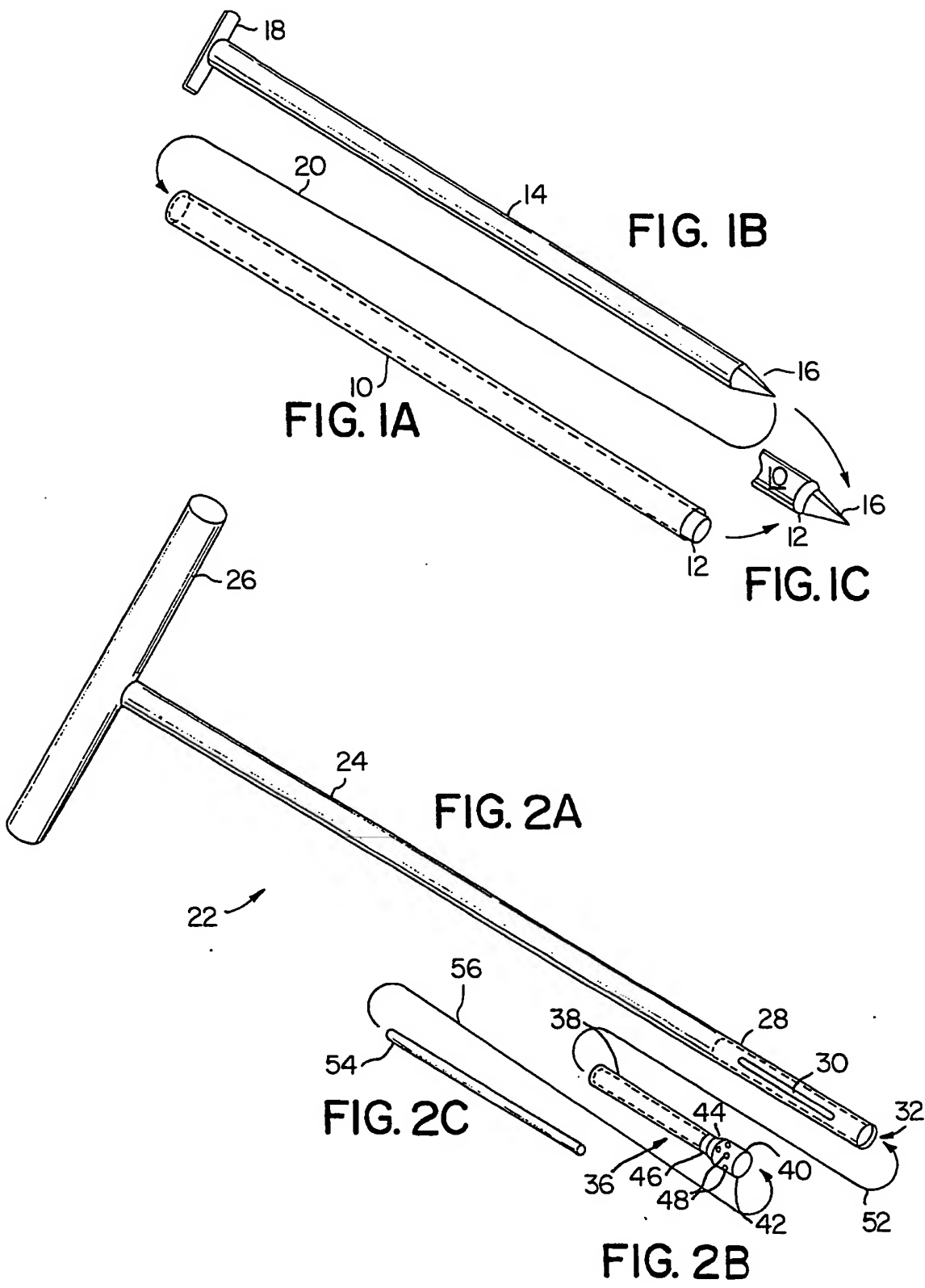
21. The method of claim 20 further comprising pushing
said cannula-enclosed starter trocar against a bone, and sawing
the bone with said cutting portion.

22. The method of claim 20 further comprising
unscrewing said specimen holder from said biopsy trocar.

WO 91/06246

PCT/US90/06268

1 / 2



WO 91/06246

PCT/US90/06268

2 / 2

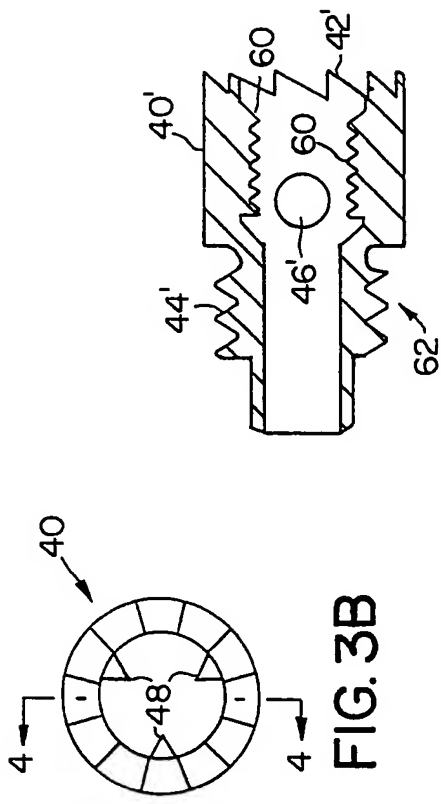


FIG. 3B

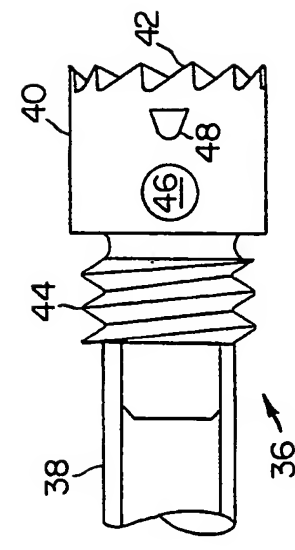


FIG. 3A

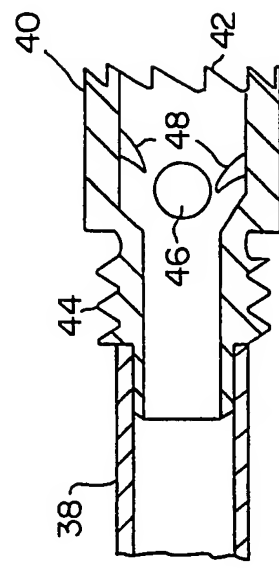


FIG. 4

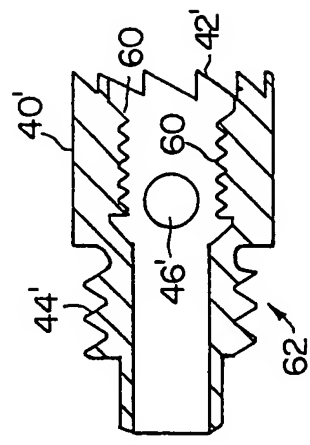


FIG. 5

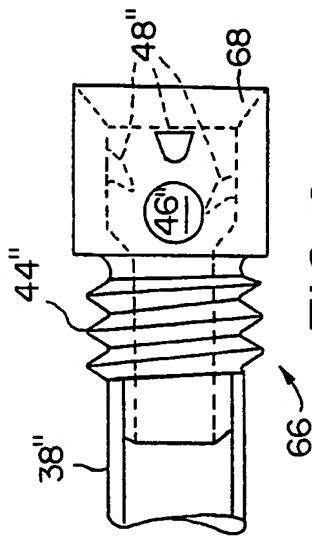


FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No PCT/US90/06268

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC(5): A61B 10/00		
U.S.CL: 128/751		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System ¹	Classification Symbols	
U.S.	128/749,751,754 30/113.1,113.2,113.3,124,278,316 606/167,170,179,180	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched ⁶		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category ⁸	Citation of Document, ¹⁴ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹⁴
X Y	US, A, 4,873,991 (SKINNER) 17 October 1989 See the entire document.	1-3,5,9,10,14,16 18 4,11-13,15,17,19
X Y	US, A, 4,798,213 (DOPPELT) 17 January 1989 See col. 5, line 50 - col. 6, line 55	20-22 4,13,17
A	US, A, 4,696,308 (MELLER ET AL) 29 September 1987 See entire document.	1-22
<p>* Special categories of cited documents: ¹³</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search ²	Date of Mailing of this International Search Report ³	
24 DECEMBER 1990	26 FEB 1991	
International Searching Authority ¹	Signature of Authorized Officer ¹⁰	
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